

Department of the Navy Human Research Protection Program

***Business Meeting and Knowledge Exchange
31 May and 1 June 2023***



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Welcome from Acting Surgeon General, United States Navy

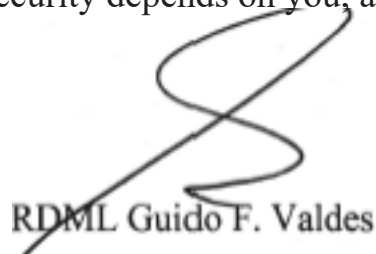
It is my pleasure to welcome you to the very first Department of the Navy Human Research Protection Program (DON HRPP) Business Meeting and Knowledge Exchange. As we prepare for future conflict and continue evolving to make sure we are ready to provide a ready medical force and operational medical capabilities in a contested battlespace, we must continue giving the warfighter every advantage possible. Research plays a critical part in that, whether we're talking about platforms, processes, or our most valuable weapons system, People. It is the latter that will drive our discussions during this meeting. Navy human subjects research must rise to the challenge of ensuring our Sailors and Marines are able to perform at their best in contested distributed maritime operations, and Navy human subjects research protections must adapt as well. This business meeting and knowledge exchange embraces the concept of Get Real Get Better, highlights medical and line research, and amplifies subject matter expertise. Ultimately, it facilitates greater connection and collaboration for higher performance. It is this pursuit of excellence and inclusion of diverse perspectives, the willingness to embrace the red and take innovative approaches that makes me proud to lead the DON HRPP, with the support of the Chief of Naval Research. As I personally approve the Assurances which set the stage for research in the years ahead, I am confident that together we will continue to ensure that Navy Medicine is able to maintain and increase the survivability and lethality of our warfighters at sea, under the sea, above the sea, and ashore. Thank you for your part in this endeavor, and for participating in this knowledge exchange.



RDML Darin Via, Acting SG

Message from Special Assistant to the Surgeon General of the Navy for Human Research Protections

Welcome to the Department of the Navy Human Research Protection Program Business Meeting and Knowledge Exchange. The importance of research—particularly human subjects research—has remained constant, it's a force multiplier. Today, as in years past, Navy Medicine ensures the medical, dental, and psychological health readiness of America's Sailors and Marines ... on, below, and above the sea, ashore, in the skies, and in space. We are actively Rendering Assistance to our warfighters. We keep them in the Fight and ensure they are operationally ready for the mission. Ultimately, we come together to ensure our warfighters lethality. Research is readiness, in addition to preparing for the highend fight, Navy Medicine has a significant role in projecting Soft Power. This is a transformational time for our Navy that comes with new challenges. Our Naval Forces are operating in a battlespace that is quickly growing in lethality, complexity, and scope. The best way to meet this challenge is through research - basic or applied. Research answers the call to create tomorrows' standard's today. We must continue to work together to answer this call and it must be answered ethically. I am proud to serve as the Special Assistant to the Surgeon General to help shape the future of the Navy's Human Subjects Research program, to provide expertise, and to facilitate the existing expertise present in this room. Our future security depends on you, and I thank you for being here.



RDML Guido F. Valdes

Welcome from Director, Department of the Navy Human Research Protection Program

Colleagues,

I am so grateful that you are joining us, whether that be in person, virtually, or asynchronously. There is no better time than now to bring our community of leaders, administrators, scientists, and human subjects research protections professionals together. The entire Department of the Navy Human Research Protection Program (DON HRPP) team has spent months preparing our first ever Business Meeting and Knowledge Exchange. We are proud to facilitate insights from Senior Navy Leadership, provide an inside look at DON HRPP operations, share knowledge from subject matter experts within DON HRPP and across the Department of Defense, and create opportunity for networking and connection. The agenda topics are meant to provide value across the spectrum- from those who lead research institutions to those performing the research. I hope you will enjoy engaging in this event as much as we have enjoyed planning it. We appreciate your dedication to continued learning and growing, and we are grateful you are here.



CDR Leedjia Svec

**Message from Director, Research Protections Division,
Office of Naval Research,
Warfighter Performance Department Code 0343,
Department of the Navy Human Research Protection Program**

The Office of Naval Research (ONR) Research Protections Division is a component of the Department of the Navy Human Research Protection Program (DON HRPP), and we are pleased to welcome you to the DON HRPP's Business Meeting and Knowledge Exchange 2023. We have a long history in supporting the Navy Surgeon General (SG) through the Chief of Naval Research (CNR) on line and medical research and our team of subject matter experts are thrilled to share their knowledge and expertise with you. The future of Navy research is a critical effort, and we are grateful to be here together to advance the protection of human subjects.

A handwritten signature in black ink, reading "Terrence Clemmons". The signature is fluid and cursive, with a long horizontal stroke at the end.

Terrence Clemmons, MS

Logistics and Useful Information

Virtual Component: The Business Meeting and Knowledge Exchange will be held on Microsoft (MS) Teams. Please sign in to MS Teams for optimal viewing and experience.

On Site:

Entrance and Parking

Visitors may enter the campus at Route 50 (7700 Arlington Blvd, Falls Church, VA 22042-5101) Access Control Point (ACP) or Fairview-Park Drive entrance on the west side of campus. Visitors arriving by cab are requested to arrive via Fairview-Park Drive entrance.

Parking passes must be printed in color and physically presented to security. Any non-marked parking spot is acceptable for parking. If entering on route 50, please drive around to the visitor entrance.

All visitors must enter the building through the Visitor Entrance I (#1) (on west side between NW and SW Buildings)



Building Information

Emergency Exits: Stairs C and D

Food and Beverage: *Mike's Deli* is located at 1SW321.
Open: 0700-1430

Restrooms: Restrooms are located at P122 and in the hallway across from 4P113.

Lactation Rooms: Lactation rooms are located at 1M105, 3NW123, and 1SW322. Please call 703-681-5744 if you need to access a lactation room.

Sanctuary: A multi-faith prayer/meditation room is located at 3M101.

Event Point of Contact: Dr. Nancy Dawood * nancy.d.dawood.civ@health.mil * 571-214-8050

Agenda at a Glance

Day 1 Session

0900-0925	Welcome, Overview, and Comments from RDML Guido Valdes, SAHRP
0925-1025	DON HRPP Overview, Updates, and Meet the DON HRPP Team
1025-1055	DON HRPP Administrator Overview
1100-1120	Remarks from RDML Darin Via, Acting Surgeon General
1120-1130	<i>Break</i>
1130-1200	DON HRPP Training and Education Overview
1200-1230	DON HRPP Quality Assurance/Quality Improvement Overview
1230-1330	<i>Lunch</i>
1330-1400	Best Practices Across DON Command HRPPs
1400-1500	Subject Matter Experts Panel Discussion on HRPP Hot Topics
1500-1510	<i>Break</i>
1510-1610	Navy Survey Program Office
1610-1650	DON HRPP Site Inspections/Assist Visits: Processes/Expectations, Findings, and Insights
1650-1700	Wrap up and Closing Remarks from CAPT Matthew Weiner

Day 2 Session

0900-0930	Welcome, Overview, and Remarks by CAPT Matthew Weiner
0930-1030	Overview of the Research Landscape with BUMED and the Office of Naval Research
1030-1100	Department of Defense Office for Human Research Protections
1100-1110	<i>Break</i>
1110-1230	Army, Air Force, Defense Health Agency, Uniformed Services University Panel: Introductions, Updates, and Working Together
1230-1330	<i>Lunch</i>
1330-1350	United States Marine Corps Human Research Protections
1350-1435	Electronic Institutional Review Board (E-IRB) with an Expert
1435-1450	Data Sharing Agreements: Questions and Answers
1450-1500	<i>Break</i>
1500-1515	Strategic Prioritization of Medical Research and Development
1515-1540	Funding Opportunities with the Office of Naval Research
1540-1555	Mapping the DON HRPP Research Landscape
1555-1650	Facilitated Networking
1650-1700	Wrap up, Appreciation, and Closing Remarks by RDML Matthew Case

Agenda at a Glance by Focus Area

Research Leadership and Strategy: Provides an overview of the current state and future directions of Navy human subjects research.

HRPP Professionals: Provides insight to DON HRPP internal operations and best practices.

Subject Matter Experts and Components: Provides perspectives direct from experts on a variety of topics spanning the spectrum of human research and human research protections.

Day 1 Session

0900-0925 Welcome, Overview, and Comments from RDML Guido Valdes, SAHRP

0925-1025 DON HRPP Overview, Updates, and Meet the DON HRPP Team

1025-1055 DON HRPP Administrator Overview

1100-1120 Remarks from RDML Darin Via, Acting Surgeon General

1130-1200 DON HRPP Training and Education Overview

1200-1230 DON HRPP Quality Assurance/Quality Improvement Overview

1330-1400 Best Practices Across DON Command HRPPs

1400-1500 Subject Matter Experts Panel Discussion on HRPP Hot Topics

1510-1610 Navy Survey Program Office

1610-1650 DON HRPP Site Inspections/Assist Visits: Processes/Expectations, Findings, and Insights

1650-1700 Wrap up and Closing Remarks

Day 2 Session

0900-0930 Welcome, Overview, and Remarks by CAPT Matthew Weiner

0930-1030 Overview of the Research Landscape with Bureau of Medicine and Surgery and the Office of Naval Research

1030-1100 Department of Defense Office for Human Research Protections

1110-1230 Army, Air Force, Defense Health Agency, Uniformed Services University Panel: Introductions, Updates, and Working Together

1330-1350 United States Marine Corps Human Research Protections

1350-1435 Electronic Institutional Review Board (E-IRB) with an Expert

1435-1450 Data Sharing Agreements: Questions and Answers

1500-1515 Strategic Prioritization of Medical Research and Development

1515-1540 Funding Opportunities with the Office of Naval Research

1540-1555 Mapping the DON HRPP Research Landscape

1555-1650 Facilitated Networking - ALL!

1650-1700 Wrap up, Appreciation, and Closing

Detailed Agenda for 31 May 2023

Day 1	Session	Speakers	Description
0900-0915	Welcome and Overview	CAPT Matthew Weiner	Join our host as he kicks off the DON HRPP B-MAKE!
0915-0925	Comments from RDML Valdes, SAHRP	RDML Guido Valdes	This presentation provides an introduction to the SAHRP as he shares his thoughts on Navy Medical R&D.
0925-1025	DON HRPP Overview, Updates, and Meet the DON HRPP Team	CDR Leedjia Svec and the DON HRPP Team	Take a deep dive into DON HRPP's role, structure, past efforts, and future activities while meeting the entire team!
1025-1055	DON HRPP Administrator Overview	Cindy Mazowieski	Learn about DON HRPP administration; from the big picture to important details that influence the Assurance renewal process and beyond.
1100-1120	Remarks from RDML Via, Acting Navy SG	RDML Darin Via	Join the Acting Navy Surgeon General as he shares his perspective on HSR and HRP.
1120-1130	<i>Break</i>		
1130-1200	DON HRPP Training and Education Overview	Katy Prendergast and Jonise Handy-Richards	Join DON HRPP T&E specialists as they present on the CITI program and provide an overview of current trainings available for request and future training efforts.
1200-1230	DON HRPP Quality Assurance/Quality Improvement Overview	Nora Livengood	Learn about DON HRPP efforts to measure what matters and Get Real Get Better with an overview of QA/QI at DON HRPP.
1230-1330	<i>Lunch</i>		
1330-1400	Best Practices Across DON Command HRPPs	CDR Leedjia Svec, Maria Badra (NAMRU-3), Zoe Moran (NAMRU-6), M. Bernadette McCann (NAMRU-D), Stepahanie Hoyer (for NAMRU-2) Miriam Arnone, Dr. M. Rochelle Collantes, Jackie Kiwanuka, Katy Prendergast	Commands across DON HRPP have a wealth of best practices. You will hear directly from them as well as Compliance Specialists/Analysts as they share what works when it comes to HRP.

Detailed Agenda for 31 May 2023

Day 1	Session	Speakers	Description
1400-1500	Subject Matter Experts Panel Discussion on HRPP Hot Topics	Jazmine Armstrong, Dr. M. Rochelle Collantes, Derek Englis, Stephanie Hoyer, Jackie Kiwanuka, Katy Prendergast <i>with Moderator:</i> Terrence Clemmons	Join expert and ONR 343 Director Terrence Clemmons as he moderates a discussion amongst DON HRPP SMEs on the topics of: <i>Reportable Events,</i> <i>International Research, Records</i> <i>Management, Consenting Process,</i> <i>Post Approval Monitoring, and</i> <i>FDA Regulated Research</i>
1500-1510	<i>Break</i>		
1510-1610	Navy Survey Program Office	Dr. Richard Linton	Hear about surveys and applicable requirements, use of survey for research within Navy and across Components.
1610-1650	DON HRPP Assist Visits/ Site Inspections: Processes/ Expectations, Findings, Insights	Miriam Arnone, Derek Englis, Nora Livengood, Jyothsna Pabba	Go beyond the usual materials presented during the AV/SI in briefs to take a behind the scenes look at the DON HRPP AV/SI process and findings.
1650-1700	Wrap up and Closing Remarks	CAPT Matthew Weiner	Review of the DON HRPP BMAKE Day 1.

***Join DON HRPP at 1800 for an informal evening of no-host socializing and good food at
Pistone's Italian Inn, 6320 Arlington Blvd., Falls Church, VA 22042***

Detailed Agenda for 1 June 2023

Day 2	Session	Speakers	Description
0900-0915	Welcome and Overview	CAPT Matthew Weiner	Join us to kick off Day 2 of the DON HRPP B-MAKE!
0915-0930	Senior Navy Leadership Remarks with CAPT Weiner	CAPT Matthew Weiner	Learn about the recent Campaign Order and the future of Navy Medicine Research.
0930-1000	Overview of the Research Landscape with BUMED	CAPT William Deniston	An overview of the NMR&D Enterprise, focusing on how NMRC provides support through Research and Development to the warfighter.
1000-1030	Overview of the Office of Naval Research	Dr. Patrick Mason	An overview of the Navy research landscape from the Office of Naval Research (ONR) perspective, presenting an introduction to ONR, areas of interest in human subjects research, current places of research, and future directions.
1030-1100	Department of Defense Office for Human Research Protections	Stephanie Bruce	Learn about all things DOHRP with a focus on Q&A.
1100-1110	<i>Break</i>		
1110-1210	Army, Air Force, Defense Health Agency, Uniformed Services University Panel: Introductions and Updates	Martha Alvarado, Jessica Candia, LTC José Pizarro, Dr. Laura Brosch	Join the COHRPS as they present how their Service engages in Human Subjects Research Protection Services.
1210-1230	Army, Air Force, Defense Health Agency, Uniformed Services University, Navy Panel: Working Together	Martha Alvarado, Jessica Candia, LTC José Pizarro, Dr. Laura Brosch CDR Leedjia Svec Terrence Clemmons <i>with Moderator:</i> Dr. Nancy Dawood	DON HRPP joins the panel to discuss a hypothetical joint research project.
1230-1330	<i>Lunch</i>		

Detailed Agenda for 1 June 2023

Day 2	Session	Speakers	Description
1330-1350	United States Marine Corps Human Research Protections	Dr. Kerry Fosher	This presentation will provide an overview of the USMC human research protection program policy and practice.
1350-1435	Electronic Institutional Review Board (E-IRB) with an Expert	Michael Coronado	An in-depth overview of E-IRB followed by Q&A.
1435-1450	Data Sharing Agreements: Questions and Answers	Clarence Abrams	This presentation provides answers to the top 8 questions DON HRPP receives regarding data sharing.
1450-1500	<i>Break</i>		
1500-1515	Strategic Prioritization of Medical Research and Development	Lt Col Claudia Eid	Where do research initiatives come from? Taking top strategy as a starting point, learn how research priorities were developed, what those priorities are, and how the Warfighter will benefit.
1515-1540	Funding Opportunities with the Office of Naval Research	Dr. Michael LaFiandra	Information on funding opportunities, who can apply for them, how to apply for them, and requirements or tips that may help those looking to obtain funding from ONR.
1540-1645	Mapping the DON HRPP Research Landscape	CDR Leedjia Svec and the BUMED Consolidated Information Center (CIC)	An exploratory application of Social Network Analysis for connection among researchers and enhanced oversight and monitoring will be presented.
1645-1650	Facilitated Networking	All	Connect with fellow colleagues by role in the session dedicated to creating opportunity for connection.
1650-1655	Wrap up, Appreciation	CAPT Matthew Weiner	A celebration of the event and all who contributed!
1655-1700	Closing Remarks by RDML Case	RDML Matthew Case	Concluding thoughts to close this historical 2-day BMAKE!



Rear Admiral Darin K. Via **Acting Surgeon General of the Navy**

Adm. Darin K. Via is a native of Illinois. He holds a Bachelor of Science in Biology from Millikin University. Via enlisted in the U. S. Navy Reserve in 1985 as a Hospital Corpsman. In 1987 he entered active duty as an Ensign at the Uniformed Services University of the Health Science, where he earned a Doctor of Medicine in 1991. Via completed a Master of Health Care Delivery Science from Dartmouth College in 2014.

Via's professional training includes a transitional internship and anesthesiology residency at the National Naval Medical Center and a trauma anesthesia fellowship at the Uniformed Services University of the Health Science, where he earned a Doctor of Medicine in 1991. Via completed a Master of Health Care Delivery Science from Dartmouth College in 2014.

Via's professional training includes a transitional internship and anesthesiology residency at the National Naval Medical Center and a trauma anesthesia fellowship at the R. Adams Cowley Shock Trauma Center, University of Maryland. He is qualified as an Undersea And Diving Medical Officer. He has served in various positions throughout Navy Medicine to include staff anesthesiologist, National Naval Medical Center and Naval Medical Center Portsmouth (NMCP); vice chairman, Uniformed Services University; Chairman, Department of Anesthesiology, NMCP; Operative Support Service Line Leader, NMCP; director for Surgical Services, NMCP; deputy commander, NMCP; and commanding officer, NMCP.

Operationally, he served as department head, Mobile Diving and Salvage Unit Two; command surgeon, Combat Support Squadron Eight; department head USNS Comfort (TAH-20) during Operation Noble Eagle; department head, Fleet Hospital Three, 1st Force Service Support Group (1st FSSG), Camp Viper, Iraq during Operation Iraqi Freedom; and commanding officer, NATO Role Three, Multi-national Medical Unit and Commander, Task Force Medical South, Kandahar, Afghanistan during Operation Enduring Freedom. Via also served as the command surgeon, U.S. Pacific Fleet, where he directed and oversaw all Force Health Protection, warfighter mission medical readiness, and strategic medical efforts in the Pacific. Via was selected the first Navy medical officer to serve as U.S. Central Command surgeon responsible for all Health Services Support in theater as the sole advisor to the Commander on all medical matters in the most kinetic combatant command.

Via's Flag tours include serving as deputy chief, Bureau of Medicine and Surgery for Operations, Plans and Readiness and he was appointed as the first medical flag officer to stand up Chief of Naval Operations (OPNAV) N44 as the single resource sponsor for expeditionary medical capabilities. He additionally served currently as commander, Naval Medical Forces Atlantic and as the senior market manager of the Tidewater Military Health System. Via began serving as the Navy deputy surgeon general; deputy chief, U.S. Navy Bureau of Medicine and Surgery; and director, Medical Resources, Plans and Policy Division, N0931, Office of the Chief of Naval Operations Jun. 30, 2022.



Rear Admiral Guido Valdes
Commander, Naval Medical Forces Pacific/Director,
San Diego Market and Chief of the Medical Corps/
Special Assistant to the Navy Surgeon General for
Human Research Protections

Rear Adm. Guido F. Valdes is a native of San Juan, Puerto Rico. He holds a Bachelor of Science in Biology from the University of Miami, Florida. He earned his Doctor of Medicine from the University of Miami School of Medicine as a Navy Health Professions Scholarship recipient and upon graduation he received his commission in 1992. His professional training includes transitional internship at the National Naval Medical Center Bethesda and emergency medicine residency at Naval Medical Center Portsmouth.

Operationally, he served as officer-in-charge of the Shock Trauma Platoon/Forward Resuscitative Surgical Site at Camp Korean Village in Al-Anbar province, Iraq during Operation Iraqi Freedom; officer-in-charge, Fleet Surgical Team Six; force surgeon, Riverine Group One; executive officer, Role 3 Multinational Medical Unit, Kandahar, Afghanistan during Operation Enduring Freedom; and force surgeon, U.S. Naval Forces Central Command/ U.S. 5th Fleet.

He has served in various positions throughout Navy Medicine to include general medical officer, Branch Health Clinic Gaeta, Italy; staff emergency physician, U.S. Naval Hospital Naples, Italy; U.S. Naval Hospital Rota, Spain; and Naval Medical Center Portsmouth; executive officer, Naval Hospital Pensacola; commanding officer, Naval Health Clinic Corpus Christi; and deputy commander, Naval Medical Forces Atlantic.

Valdes assumed duties as commander, Naval Medical Forces Pacific, May 20, 2022. He has oversight of ten Navy Medicine Readiness and Training Commands on the West Coast and Pacific Rim as well as Navy Medicine's eight global research labs. Valdes also serves under the Defense Health Agency as the director of the San Diego Medical Market where he oversees the delivery and integration of healthcare at Naval Medical Center San Diego and Naval Hospital Camp Pendleton.

Valdes is qualified as a Fleet Marine Force Warfare Officer. His personal decorations include the Legion of Merit (two awards), Meritorious Service Medal (four awards), Navy Commendation Medal (two awards), Navy Achievement Medal and various other unit and campaign awards.



**Rear Admiral Matthew Case
Director Medical Service Corps, Director;
Commander, Naval Medical Forces Atlantic**

Rear Adm. Matthew Case, is a native of Nottingham, New Hampshire. He was a direct accession and commissioned in 1994. Case received a Bachelor of Arts in English from the University of New Hampshire in 1989. He also earned a Master of Science in Health Care Administration in 1993.

He served operationally as Plans, Operations and Medical Intelligence officer with II Marine Expeditionary Force, Camp Lejeune, North Carolina and U.S. Naval Forces Europe/U.S. 6th Fleet. In 2007, Case served on an Individual Augmentee tour to Joint Task Force - Horn of Africa,

Djibouti and again in 2012 with 1st Marine Logistics Group, Helmand Province, Afghanistan.

During his ashore tours, Case served in various positions throughout Navy medicine to include administrative officer to the Director of Clinical Services at Naval Hospital Camp Lejeune, North Carolina; director for administration at Naval Ambulatory Care Center, Portsmouth, New Hampshire, Naval Health Clinic Annapolis, Maryland, Naval Hospital Camp Lejeune, North Carolina, and Naval Medical Center Portsmouth, Virginia; placement officer and assistant branch head, Medical Officer Assignment (PERS 4415) at Navy Personnel Command; and executive officer, Naval Medical Center Portsmouth, Virginia. In 2018, he assumed command of Naval Hospital Jacksonville, Florida. During this assignment he was the first commander to assume responsibility as Naval Medical Readiness Training Command commanding officer and DHA MTF director. Following his command tour in 2020, he served as executive assistant to the Surgeon General, U.S. Navy and Chief, Bureau of Medicine and Surgery in Falls Church, Virginia. In June 2022, Case assumed command of Naval Medical Forces Atlantic in Portsmouth, Virginia.

His personal decorations include the Legion of Merit, Meritorious Service Medal (six awards), Joint Service Commendation Medal, Navy and Marine Corps Commendation Medal (three awards), Navy and Marine Corps Achievement Medal (two awards), as well as the Surface Warfare Medical Department Officer qualification and Fleet Marine Force Qualified Officer designation. Case is a member of the American College of Healthcare Executives and was selected for the 2012 American Hospital Association's Federal Health Care Executive Special Achievement Award.



CAPT Matthew A. Weiner, USN, PhD

Director, Medical Information, Research, and Development

Captain Matthew A. Weiner is a native of New York. He holds a Bachelor of Arts in Biochemistry and Studio Art from Hamilton College in Clinton, New York, and a Doctorate in Microbiology and Immunology from the University of Michigan, Ann Arbor. He completed a Navy Medicine Director's Fellowship in Biodefense and is an inductee of the Scientific Research Honor Society, Sigma Xi.

For Navy Medicine, he currently serves as the Director for Medical Information, Research, and Development and as the Founding Chair of the Navy Surgeon General's Scientific Panel at the Bureau of Medicine and Surgery. He served previously as the Program Manager for Biotechnology at the U. S. Naval Research Laboratory in Washington, D.C and was the Navy Medicine Specialty Leader for Microbiology responsible for the Navy's 49-member, globally distributed community of microbiologists.

Weiner served operationally as the Director of Operations and as the Director of Threat Assessment at Navy Environmental and Preventive Medicine Unit 6 (NEPMU-6) at Joint Base Pearl Harbor Hickam, Hawaii where he worked across the INDO-PACOM Area of Responsibility. He was the Officer in Charge (OIC) of Navy Medicine's Tier 1 expeditionary asset, the Forward Deployable Preventive Medicine Unit Team Six. He deployed previously as OIC of the Navy's Deployable Ebola Detection Laboratory in Monrovia, Liberia to combat the West African Ebola outbreak in 2014/2015 and in 2006/2007 to support a Rift Valley Fever outbreak response in Garissa, Kenya.

He led Departments at the Armed Forces Radiobiology Research Institute in Bethesda, Maryland, at the Biological Defense Research Directorate at Naval Medical Research Center- Frederick, MD, and at Naval Medical Research Unit No. 3 in Cairo, Egypt where he worked throughout EUCOM, CENTCOM and AFRICOM Areas of Responsibility on threat reduction, disease surveillance, strategic cooperation, and outbreak response. His Division Officer tour was aboard Naval Medical Research Center in Silver Spring, MD.

Presenter Introductions

Dr. Patrick Mason, SES, *Office of Naval Research (ONR) Department Head for Warfighter Performance*

Dr. Patrick Mason currently serves as the Department Head for Warfighter Performance at the Office of Naval Research (ONR), Arlington, VA. He is responsible for establishing, managing, evaluating, and maintaining basic research, applied research, and advanced technology development programs to meet the operational needs of the Navy and Marine Corps.

CAPT William Deniston, USN, MSC, PhD, *Commander, Naval Medical Research Command*

CAPT Deniston serves as the Commander of the Naval Medical Research Command (NMRC). Prior to NMRC, he held command of the Naval Health Research Center (NHRC), the Department of Defense premier deployment health research center. Previously, he served as the Executive Officer of the Naval Medical Research Center (NMRC) in Silver Spring, MD which oversees seven subordinate commands, domestic and international. CAPT Deniston has numerous achievements, including having served as the Director, DON HRPP.

LTC José M Pizarro Matos, PhD, MS, *Director, Office of Research Protections, Defense Health Agency (DHA)*

LTC José Manuel Pizarro Matos is Director of Defense Health Agency (DHA) Office of Research Protections, where he establishes, manages, maintains, and oversees the daily operations of the DHA Human Research Protection Programs (HRPP) as the Director of the DHA Component Office of Human Research Protections

Lt Col Claudia M. Eid, USAF, BSC, *Joint Operations CBRN and Environmental Health Officer, Office of the Joint Staff Surgeon*

As an officer in the Joint Staff Surgeon's Office, Lt Col Eid collaborates with key stake holders to prepare strategically aligned prioritization of medical R&D initiatives to inform DHP programming guidance.

Stephanie Bruce, CIP, CPIA, *Director, DoD Office for Human Research Protections (DOHRP), Office of the Under Secretary of Defense for Research and Engineering*

Ms. Bruce serves as the Director, DOHRP whose mission is to ensure that every institution within the Department of Defense (DoD) maintains a culture of compliance with Federal laws, DoD policies, and best practices in the protection of participants in its studies.

Presenter Introductions

Clarence Abrams, *CHP Data Sharing Compliance Manager (DSCM) Defense Health Agency (DHA) Administration and Management (J-1) Privacy and Civil Liberties Office (PCLO)*

Mr. Abrams provides guidance to the enterprise on managing and safeguarding personally identifiable information as well as health information. His office enforces compliance with Federal statute and Department of Defense privacy and civil liberties related regulation and policy throughout the military health service. The DHA PCLO develops and delivers education and awareness materials and ongoing workforce and HIPAA security training.

Martha Alvarado, *Director Army Human Research Protections Office (AHRPO) Office of the Surgeon General (OTSG)*

Ms. Martha Alvarado currently serves as the Director of the Army Human Research Protections Office (AHRPO) in the Office of the Surgeon General of the Army. Prior to entering federal service in 2016, she worked at the Icahn School of Medicine at Mount Sinai's Institutional Review Board and was prior to that the Director of the Human Subjects Protections Office at Beth Israel Medical Center in New York City for 13 years. Previous work experience also includes serving as the Regulatory Coordinator for the Beth Israel Medical Center Department of Oncology and as the Clinical Trials Coordinator and Psychometrician for the Alzheimer's Disease Research Center at NYU Langone Health. A graduate of Barnard College, she completed her Master's degree in Public Health at the Mailman School of Public Health of Columbia University and has maintained her CIP certification since 2004.

Laura Brosch RN, PhD COL, ANC, USA (ret) *Assistant Vice President for Research Initiatives and Compliance- Office of the Vice President for Research Uniformed Services University of the Health Sciences (USU)*

Dr. Brosch is a retired Army Colonel and the Assistant Vice President for Research Initiatives and Compliance (AVP RIC), at the Uniformed Services University of the Health Sciences (USU) in Bethesda, Maryland. The Office of the AVP RIC enables the responsible conduct of research at USU and is responsible for USU research regulatory compliance oversight. The AVP, RIC oversees the USU Human Research Protection Program, the Animal Care and Use compliance oversight program, the Institutional Biosafety Committee and the Human Anatomical Materials Review Committee. In addition, the AVP RIC develops and monitors programs and initiatives to enhance translational research and improve collaborations. Prior to joining USU, Dr. Brosch served for over 16 years as the Director, Office of Research Protections, at the US Army Medical Research and Materiel Command (USAMRMC) at Fort Detrick, Maryland.

Presenter Introductions

Jessica Candia, JD, CIP, *Director Department of the Air Force (DAF) Component Office of Human Research Protections (COHRP) Air Force Medical Readiness Agency*

Ms. Candia is responsible for policy and oversight of human research protection for the Department of the Air Force, which includes both the United States Air Force and the United States Space Force. Ms. Candia has human research protection experience from a spectrum of Department of Defense and civilian organizations, including her current office, the Army Human Research Protections Office, the Institutional Research Office within the Air Force Research Laboratory, the Inova Health System, and the Medical University of South Carolina. In addition, Ms. Candia served as a policy expert for the Secretary of the Air Force's Publication Reduction Initiative.

Michael Coronado, *Defense Health Agency (DHA), Research and Development (J-9) Office of Research Protections*

In his role, Mr. Coronado supports the Defense Health Agency (DHA) Office of Research Protections (ORP). The DHA ORP is the human research protections program for the DHA headquarters. The Department of Defense and the DHA support and encourage research including human subjects research. The DHA ORP provides review and consultative services on human subjects determination and provides assistance throughout the protocol development and submission process.

Kerry Foshier, Ph.D., *Head of the United States Marine Corps Human Research Protection Program, Human Research Protection Official*

Dr. Kerry Foshier is the incoming head of the United States Marine Corps (USMC) Human Research Protection Program (HRPP) and will also be serving as the Marine Corps' Human Research Protection Official and Institutional Review Board Chair. Prior to joining the HRPP, she was the Director of Research for Marine Corps University. She received her PhD in cultural anthropology from the Maxwell School at Syracuse University.

Michael LaFiandra, Sc.D., *Director, Human and Bioengineered Systems Division Code 341; Director, Warfighter Protection and Applications Division Code 342, Office of Naval Research (ONR)*

As the Division Director, Dr. LaFiandra oversees program development, science and technology programs, grant portfolios, sets priorities for committing Federal funds, and acts as an advocate for specific scientific areas.

Presenter Introductions

Richard Linton, Ph.D., *Navy Survey Program Manager OPNAV N17 Culture and Force Resilience Office*

As the Navy Survey Program Manager, Dr. Linton manages, directs, and oversees the approval of all Navy surveys. He is a tireless advocate for applying experience management principles to support part of the Navy's mission to "invest in the health, readiness, capability, and the leadership ability of our force." Dr. Linton is implementing a robust listening program and is making powerful tools available across the Navy. This program provides actionable information to leaders, helping them make decisions that positively impact the sailor experience.

DON HRPP Biographies: BUMED

CDR Leedjia Svec, Ph.D., *Director, DON HRPP*

Commander Leedjia Svec studied Psychology and Engineering Technology at the University of the Pacific, studied abroad at the University of Melbourne Australia, obtained her MA/PhD in Experimental Psychology from the University of Nevada, Reno, an MA in International Relations from Saint Mary's University with distinction, and completed Joint Professional Military Education Phase I from the Naval War College with distinction. She holds certifications in Human Systems Integration from Naval Postgraduate School, Innovation Thinking from Solve Next, data visualization from UC Berkeley, vision science from Oxford University in addition to Agile, Scrum, and Lean Six Sigma training. She is the Director of DON HRPP and Specialty Leader for the Research Psychology community. Previously, she directed research for the Department of the Navy Sexual Assault Prevention and Response Office (DON SAPRO) and served as an augmentee to the Naval Inspector General, Bahrain Area Assessment and facilitated diversity and inclusion initiatives with NavalX. Prior to DON SAPRO, she was a liaison and Director of Military Programs at NASA Ames, also leading the State Department's TechWomen program for emerging leaders from Africa, Asia, and the Middle East. As senior scientist for the Defense Equal Opportunity Management Institute (DEOMI) she led policy, basic, and applied research in cultural heritage preservation, diversity and inclusion with direct influence on DoD policy. She also trained 400 service members annually as well as founding and directing DEOMI's Student Science Program. As PI at the Naval Medical Research Unit San Antonio, she developed mathematical models for predicting color vision performance in aviators wearing Laser Eye Protection while supporting research in non-lethal weapons and directed energy. She additionally served as Vice Chair for the Institutional Review Board (IRB), Chair of the Air Force Technical Review Board.

DON HRPP Biographies: BUMED

Nancy Dawood, Ed.D., *Deputy Director, DON HRPP*

Dr. Dawood is the Deputy Director, Department of the Navy Human Research Protection Program (DON HRPP). Since joining DON HRPP in 2012, she has been critical to ensuring DON HRPP carries out its responsibility to oversee and monitor DON command compliance with federal regulations and policies for the protection of human subjects engaged in research ensuring our force maintains the highest standards of performance and behavior. Dr. Dawood displays superior leadership, subject matter expertise, advocating for human research protections within Navy Medicine, shaping Navy and Department of Defense policy successfully securing continued compliance and oversight. Dr. Dawood earned her Doctorate of Education in Organizational Leadership from the College of Business at Argosy University, Schaumburg. She holds a Master of Arts in Psychology from Pepperdine University and dual Bachelor of Arts degrees (Biology and Psychology) from the University of the Southern California.

Miriam Arnone, *HRPP Compliance Specialist/Analyst*

Ms. Arnone joined DON HRPP in April 2022 and serves as the DON HRPP point of contact for 2 commands. Prior to joining DON HRPP, Ms. Arnone worked at Inova Fairfax Medical Campus, Virginia. She has over 10 years of clinical research and regulatory experience.

M. Rochelle Collantes, MPS, MPH, MD, *HRPP Compliance Specialist/Analyst*

Dr. Collantes joined DON HRPP in January 2019 and serves as the DON HRPP point of contact for 4 commands, providing human research protections (HRP) subject matter expertise for some of the largest research programs in the Navy. Prior to joining DON HRPP, Dr. Collantes supported the US Air Force (USAF) Surgeon General - Division of Research Oversight and Compliance for 3 years as an HRP Analyst. Prior to working for the USAF, she spent 6 years as a HRP specialist for the George Washington University (GWU) – Institutional Review Board (IRB). Additionally, she served a cumulative 8 years in various research roles in the clinical / translational research enterprise under the Uniformed Services University for the Health Sciences (USUHS) - Department of Surgery and the George Mason University (GMU) - Inova Translational Research Center / Center for Liver Diseases. Dr. Collantes is a Certified IRB Professional and holds a Doctor of Medicine (M.D.) from the University of the Philippines College of Medicine. She also holds a Master in Public Health (M.P.H.) in International Health Promotion and a Master in Professional Studies (M.P.S.) in Molecular Biotechnology from GWU.

DON HRPP Biographies: BUMED

Derek Englis, MBA, EdS, *Program Manager*

Mr. Englis has been a Human Research Protections Analyst at DON HRPP since January 2011, providing human research protections (HRP subject matter expertise for several programs in the Navy. Prior to joining DON HRPP, Mr. Englis was an Institutional Review Board (IRB Analyst and Research Regulatory Compliance Coordinator for the George Washington University (GWU IRB. Before that Mr. Englis worked in business. Mr. Englis holds a Master of Business Administration (MBA from the University of Utah, an Educational Specialist (EdS in Counseling from GWU, and a Bachelor of Arts (BA in International Relations from Brigham Young University.

Jonise Handy-Richards, CCRP, *Training and Education Specialist*

Ms. Jonise Handy-Richards joined DON HRPP in February 2022 and serves as the DON HRPP Training and Educational Specialist. She earned her degree in Allied Health Technology and is an active member with the Society of Clinical Research Associates (SoCRA) where she earned the title of Certified Clinical Research Professional (CCRP. Prior to joining DON HRPP, she worked at Children's National Hospital in Washington, D.C. for 22 years and has held the titles of Clinical Research Manager, Clinical Research Coordinator, and Clinical Research Specialist. She has experience in managing and overseeing complex research protocols, collaborating with the IRB, and negotiating contracts. Her management background includes the administrative management of Children's National's Clinical Research Center and its administrative staff. Ms. Handy-Richards has received over 100 IRB approvals in her research career.

Stephanie Hoyer, *HRPP Compliance Specialist/Analyst*

Ms. Hoyer joined DON HRPP in June 2022 and serves as the DON HRPP point of contact for 3 commands. Prior to joining DON HRPP, Ms. Hoyer supported the Clinical Investigation Department (CID at Naval Medical Center San Diego (NMCSD. Previously, she worked as a research coordinator at Scripps Health. She has over five years clinical research and regulatory experience.

Nora Livengood, *Quality Assurance Specialist*

Ms. Livengood began at DON HRPP as a summer intern in 2007 and has been a full-time staff member since 2010, serving in various roles. After a few years providing administrative support for the program, from 2012 to 2019 she served as the DON HRPP point of contact for several DON-Assured commands. Currently she is the DON HRPP Quality Assurance Specialist, providing data analysis, quality improvement, and other special projects for the DON HRPP program. Ms. Livengood holds a B.S. in Genetics from Clemson University.

DON HRPP Biographies: BUMED

Cynthia “Cindy” Mazowieski, *Program Administrator*

Ms. Mazowieski has been the DON HRPP Administrator since June 2009, providing administrative support to the staff and various DON HRPP Directors and Deputy Directors for the past 14 years. Prior to joining DON HRPP, Ms. Mazowieski provided administrative and event support to the Society of Vascular Technology. She also served as a meeting and event coordinator for a large commercial property management company, where she later transitioned within the company to Executive Assistant to the President, and ultimately advanced to the role of Assistant Property Manager for various properties in Maryland and the District of Columbia, most notably The Watergate Office Building. Her wealth of knowledge and administrative expertise is invaluable to the DON program.

DON HRPP Biographies: ONR 0343

Terrence Clemmons, MS, *Director, Office of Naval Research, Code 0343*

Mr. Clemmons is the Director of the Research Protections Division at the Office of Naval Research (ONR 0343 in the Warfighter Performance Science and Technology Department. Since joining ONR in 2007, he has worked in the ONR343 Division which provides oversight and monitoring of medical and non-medical human subjects research in the Navy and Marine Corps Systems Commands, operational forces, training commands, and non-Department of Defense (DoD) institutions that conduct Department of the Navy (DON)-supported research involving human subjects. By SECNAV Instruction, ONR provides support and expertise to the Surgeon General of the Navy, the single point of accountability for the DON Human Research Protection Program (HRPP). Mr. Clemmons also serves on several inter-agency, joint and Service-level panels that shape policy for DoD and DON.

Benilda Pooser, Ph.D., *Deputy Director, Office of Naval Research, Code 0343*

Dr. Pooser was newly appointed as the Deputy Director, Office of Naval Research (ONR 0343). She has a breadth of experience and professional certifications in human subjects protections.

DON HRPP Biographies: ONR 0343

Dr. N. Ismael Anoumatacky, DDS, CIP, *HRPP Compliance Specialist/Analyst*

Dr. Anoumatacky joined DON HRPP in February 2022 and serves as the DON HRPP point of contact for 2 commands. Prior to joining DON HRPP, Ismael provided subject matter expertise support to the Congressional Directed Medical Research Program (CDMRP of the United States Army Medical Research and Development Command USAMRDC), Office of Research Protection (ORP), Office of Human Research Oversight (OHRO. Previously, Ismael worked as Senior Clinical Research Associate (CRA and Senior Human Subject Protection Scientist (HSPS supporting the National Institute of Allergy and Infectious Diseases (NIAID research program. Ismael holds a Doctorate in Dental Surgery and professional certification as a Certified Institutional Review Board (IRB) Professional (CIP). He has over 20 years of clinical practice, research, and regulatory experience combined.

Jazmine Armstrong, MS, CIP, *HRPP Compliance Specialist/Analyst*

Ms. Armstrong joined DON HRPP in January 2022. Prior to joining DON HRPP, Ms. Armstrong served as an Institutional Review Board (IRB) analyst at The Children's Hospital of Philadelphia in Philadelphia, PA and senior regulatory analyst at The University of Texas Southwestern Medical Center in Dallas, TX. She holds a Bachelor of Science Degree in Biology, Master of Science Degree in Biomedical Sciences, and a professional certification as a Certified Institutional Review Board (IRB) Professional (CIP. In previous roles, Ms. Armstrong gained extensive knowledge regarding human subjects' research protections in biomedical and social-behavioral research and a working knowledge of Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP) regulated research. In addition, Ms. Armstrong has led educational sessions related to various aspects of human research regulations, and the IRB review and approval process. Before her work in human research protections, Ms. Armstrong conducted human factors research, focusing on correlations between behavior and hemodynamic responses as validation markers for skill acquisition and mastery.

Monai Carter, *Administrator, ONR 0343*

Monai Carter is an Executive Assistant for the ONR Code 0343 program that supports DON HRPP. Ms. Carter joined ONR in November 2022. She comes over from the Defense Health Agency where she supported the J5 Analytics and Evaluation Team as well as J3 Clinical Health Women's Division. She has a bachelors in Criminal Justice and Criminology from Purdue University. Prior to contracting, she was a federal civilian 4.5 years on Andrews Air Force Base supporting the 316th Squadron as Child Youth Program Assistant/Admin. She has over 6+ years working in the federal government and supporting high level clients.

DON HRPP Biographies: ONR 0343

Eric Fried, JD, *Associate Counsel ONR, Counsel to the DON HRPP*

Mr. Fried provides legal expertise reviewing proposed policies and other work products. He has supported DON HRPP as legal counsel providing many years of experience and knowledge in the area of human subjects research and the protection of human subjects.

Jacqueline “Jackie” Kiwanuka, MBA, CIP, *HRPP Compliance Specialist/Analyst*

Ms. Kiwanuka joined the DON HRPP in December 2021 and serves as the DON HRPP point of contact for 4 commands. She has over 14 years of experience with human research protections in biomedical and social and behavioral research. Prior to joining DON HRPP, Ms. Kiwanuka served as the Senior Regulatory Associate with the Gynecologic Cancer Center of Excellence, Women’s Integrated Health Research Center, under the Henry M. Jackson Foundation for the Advancement of Military Medicine. She holds a Bachelor’s degree in Biochemistry and a Master’s degree in Business Administration with a Healthcare Finance concentration, and is a Certified Institutional Review Board (IRB) Professional (CIP®). Prior to her position at the Women’s Health Integrated Research Center, Ms. Kiwanuka worked under General Dynamics Health Solutions as a Human Subjects Protection Scientist, the Team Lead at the US Army Medical Research & Development Command (USAMRDC) Human Research Protection Office, and at the Defense Health Agency (DHA) HRPP as a Subject Matter Expert. Prior to her work with General Dynamics, she spent 10 years at the University of Maryland’s Psychiatric Research Center supporting neuropsychology and clinical trial studies as a Clinical Laboratory Manager.

Jyothsna Pabba, *HRPP Compliance Specialist/Analyst*

Ms. Pabba joined DON HRPP in November 2022 and serves as the DON HRPP point of contact for 2 commands. Prior to joining DON HRPP, Jyothsna served as Human Subjects Protection Scientist (HSPS) contract support to the Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO) of the United States Army Medical Research and Development Command (USAMRDC) where she conducted regulatory reviews of complex human subject research protocols, providing subject matter expert guidance and recommendations to OHRO. In previous roles, Jyothsna worked as HSPS for Technical Resources International (TRI) Inc., Bethesda, MD; Clinical Project Lead, clinical operations for Bioclinica, Princeton, NJ; and Licensed Practical Nurse (LPN) for Waters Edge Health Care and Rehabilitation Center, Trenton, NJ. Jyothsna holds a Bachelor’s degree in Microbiology. She has over 10 years of clinical, research, and regulatory experience combined.

DON HRPP Biographies: ONR 0343

Kathleen “Katy” Prendergast, MS, CCRP, *HRPP Compliance Specialist/Analyst*
Ms. Prendergast joined the DON HRPP in April 2021 and serves as the DON HRPP point of contact for 4 commands. Prior to joining the DON HRPP, Ms. Prendergast spent three years as a Sr. Clinical Trial Budget Developer for AbbVie. She has over 10 years of research experience in biomedical, social, and behavioral research. In addition to her years at AbbVie, she also held various research positions at the University of Chicago and Northwestern University. She holds a Master of Science from Northwestern University in Clinical Research and Regulatory Administration, and is a Certified Clinical Research Associate (SOCRA®).



The DON HRPP team prepares for the 2023 BMAKE.

DON HRPP Key Information at a Glance

DON HRPP General Phone Number: 703-681-9629

DON HRPP General Mailbox: usn.ncr.bumedfchva.mbx.don-hrpp@health.mil

The Office of Naval Research (ONR) Research Protections Division:

usn.pentagon.cnr-arlington-va.mbx.onr-343@us.navy.mil

DON HRPP milSuite Group: <https://www.milsuite.mil/book/groups/don-hrpp>

DON HRPP Website: <https://www.med.navy.mil/About-Us/Human-Research-Protection-Program/>

The Office of Naval Research (ONR) Research Protections Division Website:

<https://www.nre.navy.mil/work-with-us/how-to-apply/compliance-and-protections/research-protections>

Appreciation

The DON HRPP thanks everyone who contributed to this event and all who attended. We could not have done it without you!

Speakers and Presenters:

RDML Darin Via, Acting SG
RDML Guido Valdes, SAHRP
RDML Matthew Case
Patrick Mason, Ph.D., SES
CAPT William Deniston, Ph.D.
CAPT Matthew Weiner, Ph.D.
LTC José M Pizarro Matos, PhD, MS
Lt Col Claudia Eid
CDR Leedjia Svec, Ph.D
Clarence Abrams
Martha Alvarado, MPH, CIP
Jazmine Armstrong, MS, CIP
Miriam Arnone
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Stephanie Bruce, CIP, CPIA
Jessica Candia, JD, CIP
Monai Carter
Terrence Clemmons, MS
M. Rochelle Collantes, MPS, MPH, MD
Michael Coronado
Nancy Dawood, Ed.D.
Derek Englis, MBA, EdS
Kerry Foshier, Ph.D.
Jonise Handy-Richards, CCRP
Stephanie Hoyer
Jacqueline Kiwanuka, MBA, CIP
Michael LaFiandra, Sc.D.
Richard Linton, Ph.D.
Nora Livengood
Cindy Mazowieski
Jyothsna Pabba
Kathleen Prendergast MS, CCRP

Thank you to the following commands who traveled to attend in person:

Manpower & Reserve Affairs
Naval Medical Research Unit San Antonio
Naval Postgraduate School
Naval Surface Warfare Center Dahlgren
Naval Experimental Dive Unit
Naval Information Warfare Center Atlantic
Naval Medical Research Command
United States Marine Corps

Best Practices Submitted/Presented by:

NAMRU-2
NAMRU-3 / Maria Badra
NAMRU-6 / Zoe Moran
NAMRU Dayton / M. Bernadette McCann

*We extend our
gratitude to your
commitment and
dedication to the
protection of human
subjects in research.*

Volunteers

*DON HRPP is especially grateful for **CDR Leedjia Svec, Dr. Nancy Dawood, Ms. Cindy Mazowieski, and Ms. Nora Livengood** who worked tirelessly behind the scenes to make this event successful.*

*DON HRPP extends extra gratitude to **Dr. Nancy Dawood** who fearlessly led the execution of this event.*

*In addition to the entire **DON HRPP Team** and **Navy Medicine Leadership**, we also extend our appreciation to:*

CAPT Matthew Weiner
LTC Mark Chappell
CDR Paul Hauerstein
LCDR Irina Etobayeva
LCDR Joshua Swift
MC1 John Grandin
HM1 Willie James
HM1 Holden Roberts
SFC Robert Parrott
SFC Jamie Jackson
Tyrone Baugh
Raul Bonilla
John Bracey
Kathy Coates
Melza Doores-Sykes
Kelley Goodwin
Amina Jamil
Tim Linder
Dallanara Noriega
Michael Rhode
Kylan Small
André Sobocinski
Sherry White-Royal
BUMED Consolidated Information Center
and all others who contributed.

Networking Notes

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Thank you for joining us!